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VIA ELECTRONIC FILING

The Honorable Leonard P. Stark
United States District Court
J. Caleb Boggs Federal Building
844 King Street
Wilmington, DE 19801

Re: *454 Life Sciences Corporation v. Ion Torrent Systems, Inc., et al.*
C.A. No. 15-595-LPS

Dear Chief Judge Stark,

We write on behalf of plaintiff 454 Life Sciences Corporation (“454”) concerning disputed aspects of the Protective Order in this case. A draft proposed Protective Order, setting forth the parties’ respective proposals, is attached as Exhibit A.

I. Factual Background

This litigation concerns three patents, owned by 454, directed to a technique called “bead emulsion amplification” (which includes an embodiment called “emulsion PCR”) for copying (“amplifying”) nucleic acids, such as DNA, and sequencing the resulting amplified nucleic acids. 454’s First Amended Complaint, filed December 1, 2015, alleges that Defendants infringe the patents-in-suit both directly and indirectly by selling machines and consumables that induce and contribute to unauthorized use of the claimed methods and of the products (“decorated beads”) produced by the claimed methods.

On December 30, 2015, Defendants filed three (3) petitions with the United States Patent and Trademark Office (“USPTO”) seeking *inter partes* review (“IPR”) of all the claims of the three Patents-in-Suit. Defendants’ IPR petitions contend that the cited prior art allegedly renders the claims of the patents-in-suit invalid under 35 U.S.C. §§ 102 or 103. On June 3, 2016, Defendants served their initial invalidity contentions including the same grounds of invalidity that they assert in their IPR petitions presently pending before the USPTO.

II. The Protective Order Disputes

A. Use of discovery materials in parallel IPR proceedings

Defendants seek to prohibit use of relevant discovery materials in parallel IPR proceedings. 454 objects to this proposed restriction and asks that the Protective Order should not prohibit use of discovery materials in parallel IPR proceedings that are commenced by the Defendants or their affiliates. *See Exhibit A, ¶ 2.*

Defendants are seeking to litigate by way of IPR proceedings the merits of certain of the same defenses to 454’s claims that Defendants also assert in this action. 454 submits that Defendants are not entitled to prohibit use of confidential information that Defendants produced in this litigation in the IPR proceedings that Defendants initiated.

Discovery is proceeding in this case, and will include information relating to

“commercial success, long felt but unsolved needs, failure of others, etc.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). It is undisputed that discovery of evidence relevant to Defendants’ asserted invalidity defenses will occur. The only dispute is whether *use* of *discoverable* evidence relevant to those defenses will be restricted to just one of the two fora where Defendants are simultaneously attacking the validity of the patents-in-suit.

Defendants have presented no legitimate basis for the Protective Order restriction they seek. Under 37 C.F.R. § 42.54, discovery materials in IPR proceedings are permitted to be filed under seal in the USPTO. The Protective Order proposed by 454 would not affect the scope, timetable, or conduct of any IPR proceedings. The Protective Order would merely leave the parties free to *proffer* to the USPTO, for whatever probative value the USPTO might deem it to have, evidence obtained in discovery in this case.

If the Court imposes the prohibition that Defendants seek, the inevitable result would be to hamper 454 from presenting a complete defense of the patents-in-suit in parallel IPR proceedings. The prohibition would result in wasteful duplication of discovery efforts and multi-front litigation of discovery disputes in this Court and before the USPTO, with neither forum having complete control over the matter. Moreover, a Protective Order that includes such a use limitation might directly conflict with 454’s duty of candor to the USPTO.

Defendants have cited no case, and the undersigned is aware of none, in which a Protective Order has been issued, over the objection of the patent owner, to prohibit use of discovery materials in aid of a parallel proceeding between the same parties involving the same issues. Indeed, this Court recently adjudicated this exact issue in a patent case and declined to impose the prohibition that Defendants seek here. *See D.I. 36 in Pregis Innovative Packaging Inc. v. Sealed Air Corp.*, C.A. No. 13-1084 (LPS) (D. Del.) (“The Court agrees with Plaintiff that there is no reason for this Court to place any restriction on what material the USPTO/PTAB may wish to consider in connection with IPR proceedings pending before it. The intent and effect of the Protective Order the Court will enter is to permit any party to proffer to the PTAB any discovery material from the instant litigation, but without in any way affecting the PTABs ability to interpret and enforce its own rules and procedures.”).

Even where (unlike here) complete strangers to a case seek access to discovery materials for use in parallel litigation, courts have repeatedly recognized that: “Allowing the fruits of one litigation to facilitate preparation in other cases advances the interests of judicial economy by avoiding the wasteful duplication of discovery. *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1131 (9th Cir. 2003). *See also Wolhar v. General Motors Corp.*, 712 A.2d 464, 469 (Del. Super. 1997) (“In circumstances where . . . parties seek modification of a protective order to avoid duplicative discovery, courts have further held that such modification can be denied only where it would tangibly prejudice substantial rights of the party opposing modification.”).

In sum, the Protective Order prohibition sought by Defendants is without justification in law or fact. Insofar as discovery produced in this case is relevant to the invalidity defenses that Defendants have raised in parallel USPTO proceedings, that discovery should be available for potential use in both proceedings.

B. Access by in-house counsel to “Highly Confidential” material

The parties have agreed that the Protective Order should provide for two levels of confidentiality, with the most sensitive commercial information being designated “Highly Confidential – Attorneys’ Eyes Only” while less sensitive proprietary information is designated as “Confidential.” The parties agree that designated in-house counsel should have access to information that is “Confidential” but disagree on whether in-house counsel should have access

“Highly Confidential” information of an adversary. *See Exhibit A, ¶ 3(a)(6).*

454 believes that in-house counsel should not have access to “Highly Confidential” information, for two reasons. First, there is a substantially higher risk that such information will be accessed (even inadvertently) if it is maintained on Defendants’ (rather than outside counsel’s) data management systems in the electronic form in which it will be produced. Second, if Defendants are in possession of Highly Confidential documents, it is likely that they will have to be collected and reviewed for purposes of other concurrent litigations. Even if Defendants have elected to utilize an in-house attorney more actively than most litigants do to defend this litigation, 454 should not bear the burden (and the risk) of exposure of its “Highly Confidential – Attorneys’ Eyes Only” productions to accommodate Defendants’ atypical legal staffing choices. Accordingly, Highly Confidential information should be available to outside counsel, but not to in-house counsel who are permitted to receive “Confidential” information.

C. The scope and applicability of the patent prosecution bar

The parties disagree about the scope of the patent prosecution bar in the Protective Order.

454 proposes that the patent prosecution bar should cover patents and applications with claims directed to “**bead emulsion amplification (e.g. emulsion PCR) or detection or sequencing of nucleic acids amplified by bead emulsion amplification.**” Exhibit A, ¶¶ 3(a)(1) & 3(b)(2). This restriction is tailored to correspond to the subject matter of the patents-in-suit. Defendants propose a much broader bar, which would cover to any patent that involves “**subject matter related to nucleic acid detection of sequencing, including library preparation, template preparation, sequencing, and sequence analysis and reporting.**” Exhibit A, ¶ 3(a)(1). The broad bar proposed by Defendants extends far beyond the needs of this case to include all nucleic acid detection and sequencing, including ways of sequencing and detecting DNA that existed before the technology of the patents-in-suit was developed. This would severely hamper the ability of 454’s designated in-house counsel to discharge their ordinary duties regarding technologies that have nothing whatsoever to do with the subject matter of the claims actually asserted in this action.

454 also proposes that the patent prosecution bar should apply to both outside and in-house counsel who receive Confidential Information, whether designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL. Defendants would exempt in-house counsel who receive CONFIDENTIAL information from the patent prosecution bar. *See Exhibit A, ¶(b)(2).* There is no justification for permitting in-house counsel who engage in the barred activities from obtaining an adversary’s Confidential Information, and Defendants have identified none.

D. Claw-back of allegedly privileged information after inadvertent production

Defendants propose a claw-back provision that departs sharply from Fed. R. Civ. P. 26. Rule 26(b)(5)(B) permits a party that receives a document in production that the producing party later contends to be privileged to “return, sequester, or destroy the specified information” until any dispute as to privilege has been resolved by the parties or by the Court. Defendants would have this Court write “sequester” out of Rule 26(b)(5)(B) by requiring by a party to **return or destroy** documents produced in discovery immediately upon receipt of a notice contending that the documents were privileged and inadvertently produced – even if the privileged status is disputed. Defendants would even require immediate destruction of work product that discusses an allegedly-privileged document. 454 believes that such a departure from the Rule is unwarranted, would hamper the ability of a receiving party who challenges a privilege designation to resolve the dispute to its satisfaction informally by discussion, or if need be, to seek the aid of the Court, and would result in irretrievable loss of work product even if the document in question is determined not to be privileged.

Respectfully,
/s/ Stephanie E. O'Byrne
Stephanie E. O'Byrne

SEO:nmt/1226279/42322

Enclosure

cc: Clerk of the Court (Via Hand Delivery, w/encl.)
Counsel of Record (Via Electronic Mail, w/encl.)